

REMARKS

Entry of this Amendment is proper under 37 C.F.R. § 1.116, because the Amendment places the application in condition for allowance for the reasons discussed herein; does not raise any new issue requiring further search and/or consideration, because the amendments amplify issues previously discussed throughout prosecution; does not present any additional claims; and places the application in better form for an appeal should an appeal be necessary. The Amendment is made in response to arguments raised in the final rejection. Entry of the Amendment, reexamination and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.116, are thus respectfully requested.

As indicated in the Office Action Summary, Claims 1-28 were pending in the application. Claims 1-13 were under consideration. Claims 14-28 were withdrawn from consideration.

The Office Action Summary indicates that Claims 1-13 stand rejected. However, at page 2-3 of the Official Action, it is indicated that the former rejections of Claims 1-13 under 35 U.S.C. §§ 101 and 112 have been withdrawn. These were the only rejections that applied to Claims 1-8. No new reasons for rejecting Claims 1-8 are found in the Detailed Action. Therefore, it is believed that Claims 1-8 are allowable, and only Claims 9-13 were rejected in the instant Office Action.

By way of the instant Amendment, Claims 11-28 have been canceled without prejudice or disclaimer to the subject matter disclosed therein. Claims 1, 4, 5, 8, 9 and 10 are amended. The amendments to Claims 1, 4, 5, 8 and 9 simply expand the contraction

"B." to *Bacterioides*, correct typographical errors, and place recited Markush groups into proper grammatical form. Support for the amendment to Claim 10 can be found throughout the Specification, for example at page 3, line 20 to page 4, line 5, at page 9, lines 3-23, and at page 11, lines 18-25. No prohibited new matter has been introduced by way of the instant amendment. Applicant reserves the right to file a continuation or divisional application on the canceled subject matter.

Interview Summary:

Applicant thanks the Examiner for the courtesy of a telephonic interview with the undersigned representative on January 15, 2004. The status of the pending claims was discussed. Applicant understands that an agreement was reached with respect to Claims 1-9, specifically that Claims 1-9 were allowable as presented. Applicant believes that the grammatical amendments to Claims 1, 4, 5, 8 and 9 presented herein do not affect this agreement.

Objection to the Specification:

The Examiner has objected to the title for reciting "NUCLEIC ACID AND AMINO ACID SEQUENCES" while the elected claims are directed to nucleic acids. Applicant submits that the title is descriptive of the subject matter disclosed in the specification and notes that Claim 1 is directed to a nucleic acid that encodes an amino acid sequence. However, simply in order to expedite prosecution, the title has been amended to strike the words "AND AMINO ACID." Accordingly, withdrawal of the objection is respectfully requested.

Rejections Indicated as Withdrawn:

In the paragraph bridging pages 2-3 of the Official Action, the Examiner has indicated that the rejections addressed by sections I and II (pages 4-11) of the Amendment and Response filed May 13, 2003 have been withdrawn. Thus, the former rejections of Claims 1-13 under 35 U.S.C. §§ 101 and 112 for alleged lack of utility have been indicated as withdrawn.

Applicant understands that only the rejections of Claims 9-13 specifically addressed in the present Official Action were maintained.

Claim Rejections Under 35 USC § 112, First Paragraph:

I. Claims 9 and 10

At pages 3-6 of the Official Action, Claims 9 and 10 have been rejected under 35 U.S.C. § 112, first paragraph as allegedly containing subject matter not described in the specification in such a way as to reasonably convey to one of skill in the art that the inventors, at the time the application was filed, had possession of the invention.

In the Official Action, Claims 9 and 10 have been rejected together, for apparently the same reasons. In stating the alleged reasons for the rejection, the Examiner has construed Claims 9 and 10 as follows: At page 3 of the Official Action, the Examiner asserts "claims 9 and 10 . . . are drawn to a genus, i.e., any 20 or 40 nucleotides capable of hybridizing to a sequence set forth in SEQ ID NO:4084, a complement of SEQ ID NO: 4084, or an RNA of the same wherein U is substituted for T." At page 4, the Examiner

further states "the probe or isolated nucleic acid could encompass any nucleic acid minimally containing SEQ ID NO: 4084". The Examiner alleges that this subject matter is not adequately described in the Specification. The rejection is respectfully traversed.

A. Regarding Claim 9

Claims 9 and 10 do not recite identical subject matter.

The reasons alleged for rejecting Claims 9 and 10 are clearly not applicable to Claim 9. Claim 9 recites a "probe comprising a nucleotide sequence consisting of at least twenty contiguous nucleotides of a nucleotide sequence selected from the group consisting of: (a) SEQ ID NO: 4084; (b) a complement of SEQ ID NO: 4084; or (c) an RNA of (a) or (b), wherein U is substituted for T. Thus, Claim 9 is directed to "probes."

The term probe is defined in the Specification at page 9, lines 26 to 28. There, the Specification discloses:

"[T]he term "probe" refers to a nucleic acid, peptide, or other chemical entity which specifically binds to a molecule of interest. Probes are often associated with or capable of associating with a label."

Claim 9 is directed to a "probe" comprising a defined "nucleic acid sequence." The nucleic acid sequence element of the probe of Claim 9 is precisely described. The nucleic acid sequence consists of at least twenty contiguous nucleotides of SEQ ID NO: 4084, its complement, or an RNA thereof, i.e. from twenty nucleotides to the full length of SEQ ID NO: 4084, its complement, or an RNA thereof. Because SEQ ID NO: 4084 is precisely described in the Sequence Listing, the chemical structure of every such nucleic acid sequence can be logically derived from this description. Thus, the chemical structure of

every species of the nucleic acid element recited in Claim 9 is adequately described in the Specification.

In accordance with the definition in the Specification, the probe of Claim 9 may comprise additional elements, such as a label, which are common in such probes. As disclosed at page 19, line 28 to page 20, line 3 of the Specification:

“A label is a chemical moiety capable of detection. Typical labels comprise dyes, radioisotopes, luminescent and chemiluminescent moieties, fluorophores, enzymes, precipitating agents, amplification sequences, and the like.”

A skilled practitioner would have been familiar with such labels and the manner in which such labels could be associated with a nucleic acid sequence at the time the application was filed.

Therefore, Claim 9 encompasses “probes” as defined in the specification comprising a fully described genus of nucleic acid sequences and such other chemical moieties as are consistent with a probe. From the foregoing, it is clear that the subject matter of Claim 9 is adequately described in the specification in such a way as to reasonably convey to one of skill in the art that the inventors, at the time the application was filed, had possession of the invention. Accordingly, withdrawal of the rejection of Claim 9 under 35 U.S.C. § 112, first paragraph, is respectfully requested.

B. Regarding Claim 10

Claim 10, as presently amended, recites an isolated nucleic acid encoding a *B. fragilis* polypeptide of at least 10 consecutive amino acids of SEQ ID NO: 9306, wherein

the nucleic acid is hybridizable to a nucleic acid having a nucleotide sequence selected from the group consisting of: (a) SEQ ID NO: 4084; (b) a complement of SEQ ID NO: 4084; and (c) an RNA of (a) or (b), wherein U is substituted for T. Description of the subject matter of Claim 10, as amended, can be found throughout the Specification, for example at page 3, line 20 to page 4, line 5, at page 9, lines 3-23, and at page 11, lines 18-25., and in the disclosure of SEQ NOS: 4084 and 9036.

Claim 10 is directed to a nucleic acid that encodes a *B. fragilis* polypeptide that is at least a fragment of SEQ ID NO: 9306, the polypeptide encoded by SEQ ID NO: 4084. Thus, the polypeptide encoded by the nucleic acid has at least 10 consecutive amino acids of SEQ ID NO: 9306. Since the sequence of SEQ ID NOS: 9306 and 4084 are fully described in the Specification, the essential structural features of the genus of claimed nucleic acids can be deduced from the description in the Specification by one of skill in the art.

Furthermore, the nucleic acid of Claim 10 must be hybridizable to a nucleic acid having a nucleotide sequence selected from the group consisting of: (a); SEQ ID NO: 4084; (b) a complement of SEQ ID NO: 4084; and (c) an RNA of (a) or (b), wherein U is substituted for T.

One of skill in the art would have been familiar with the structural requirements for hybridization of a nucleic acid to a specific sequence at the time the application was filed. Thus, this requirement further defines the structural characteristics of the claimed nucleic acids.

From the foregoing, it is clear that the subject matter of Claim 10 is described in the specification in such a way as to reasonably convey to one of skill in the art that the inventors, at the time the application was filed, had possession of the invention.

Accordingly, withdrawal of the rejection of Claim 10 under 35 U.S.C. § 112, first paragraph, is respectfully requested.

II. Claims 11-13

At pages 6-8 of the Official Action, Claims 11-13 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly containing subject matter not described in the specification in such a way as to reasonably convey to one of skill in the art that the inventors, at the time the application was filed, had possession of the invention.

Without agreeing with the alleged reasons for the rejection, but simply in order to expedite prosecution of the application, Claims 11-13 have been canceled. Thus, the rejection is moot.

CONCLUSION

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

In the event that there are any questions relating to this application, it would be appreciated if the Examiner would telephone the undersigned concerning such questions so that prosecution of this application may be expedited.

In the event further fees are due to maintain pendency of this application, the Examiner is authorized to charge such fees to Deposit Account No. 02-4800.

Respectfully submitted,

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